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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/543,109

07/22/2005

Dieter Dorsch

Merck-3039

5468

23599 7590 06/05/2008
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EXAMINER

ANDERSON, REBECCA L

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

06/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/543,109

Applicant(s)

DORSCH ET AL.

Examiner

REBECCA L. ANDERSON

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-24 are currently pending in the instant application and are subject to a lack of unity requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous and widely divergent subject matter claimed, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I Claims 1-16 and 18-21 drawn to products of the formula I wherein D is phenyl; X is NR₃; Y is alkylene and T is monocyclic carbocycle.

Group II Claims 1-16 and 18-21 drawn to products of the formula I wherein D is phenyl; X is NR₃; Y is alkylene and T is bicyclic carbocycle.

Group III Claims 1-16 and 18-21 drawn to products of the formula I wherein D is phenyl; X is NR₃; Y is alkylene and T is monocyclic heterocycle.

Group IV Claim 17 drawn to process a) of preparing products of the formula I wherein D is phenyl; X is NR₃; Y is alkylene and T is bicyclic heterocycle.

Group V Claim 17 drawn to a process b) of preparing products of the formula I wherein D is pyridyl; X is NR₃; Y is alkylene and T is bicyclic heterocycle.

Group VI Claim 17 drawn to a process c) of preparing products of the formula I wherein D is pyridyl; X is O; Y is alkylene and T is bicyclic heterocycle.

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Group VII Claims 22 and 24 drawn to processes of preparing medicaments with products of the formula I wherein D is pyridyl; X is O; Y is cycloalkylene and T is bicyclic heterocycle.

Group VIII Claim 23 drawn to kits comprising products of the formula I wherein D is pyridyl; X is O; Y is Het-diyl and T is bicyclic heterocycle.

(It is noted that claims 22 and 24 are improper "use" claims according to 35 USC 101 and have been interpreted as processes of preparing medicaments for the instant lack of unity requirement)

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Again, this list is not exhaustive as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product or a process of preparation) by identifying another specific embodiment of similar scope to the exemplary groups which is not listed in the exemplary groups of the invention and examiner will endeavor to group the same. The applicant may also choose to elect a single disclosed species or a single discloses species for a procecc and the examiner will endeavor to create a group comprising the elected species of similar scope to the exemplary groups.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a)

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Groups I-VIII lack unity of invention since under 37 CFR 1.475: the technical feature corresponding to the claims is $\text{HN-C(O)-[N or O]-CH}_2\text{-C(O)-N}$. This technical feature is not a special technical feature because it fails to define a contribution over the prior art as can be seen by WO 02/48099, page 1, formula I, provided by applicant on a 1449. Therefore claims 1-24 are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a special technical feature as the technical feature present fails to define a contribution over the prior art. Additionally, the variables found on the $\text{HN-C(O)-[N or O]-CH}_2\text{-C(O)-N}$ vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter. Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical feature, the claims lack unity of invention and should be limited to only a product or a method of preparation.

Furthermore, in regards to groups I-VIII even if unity of invention under 37 CFR 1.475(a) is not considered lacking, which it is, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be

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considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

And, according to 37 CFR 1.475(c)

if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

Therefore, since the claims are drawn to more than a product and a process of preparation, and according to 37 CFR 1.475 (e)

the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

The claims, therefore, lack unity of invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/
Primary Examiner, AU 1626*

3 June 2008

Rebecca Anderson
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